IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION **THIS DOCUMENT RELATES TO:** **WAVE 1 CASES LISTED IN EXHIBIT A**	**Master File No. 2:12-MD-02327** **MDL No. 2327** **JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

PLAINTIFFS' REPLY IN SUPPORT OF PLAINTIFFS' DAUBERT MOTION TO EXCLUDE CERTAIN OPINIONS AND TESTIMONY OF DEFENSE EXPERT REBECCA M. RYDER, M.D.

NOW COME Ethicon Wave 1 Plaintiffs listed in Exhibit "A" attached to Plaintiffs' *Daubert* Motion [ECF No. 2016] ("Mot.") and respectfully submits this Reply in support of their Mot. and Memorandum of Law in Support of *Daubert* Motion to Exclude Certain Opinions and Testimony of Defense Expert Rebecca M. Ryder, M.D. [ECF No. 2021] ("Mem.").

ARGUMENT

I. Opinions Regarding Defective Design

Plaintiffs seek exclusion of Dr. Ryder's opinions regarding defective design on the grounds that she is unqualified to render such opinions and the lack of a reliable, scientific basis. (Mem. at 10). Plaintiff's argument that Dr. Ryder is unqualified is not limited to Dr. Ryder's lack of "train[ing] in a device manufacturer's internal workings in bringing a new device to market" as Defendants contend in their Response. Resp. to Pls.' Mot. to Exclude Certain Ops. and Test. of Dr. Ryder ("Resp.") [ECF No. 2154] at 7. Rather, Plaintiffs' argument is based on Dr. Ryder's CV and her deposition testimony regarding her qualification, knowledge, and basis for her opinion.

(Mem. at 10-11). Defendants' counter-argument is centered on Dr. Ryder's experience in light of this Court's holding in *In re C.R. Bard, Inc.*, 948 F. Supp. 2d 589, 612 (S.D. W. Va. 2013). (Resp. at 7-8). However, *Tyree v. Bos. Sci. Corp.*, No. 2:12-cv-08633, 2014 U.S. Dist. LEXIS 148312 (S.D. W. Va. Oct. 17, 2014), is more akin to the facts here. For instance, like the expert in *Tyree*, *id.* at 176, Dr. Ryder stated that she is not an expert in the design of Prolift, Pls.' Mot. Ex. D, Dr. Ryder 3/21/16 Dep. Tr. ("Ryder Dep. Tr.") at 106:18-20. Dr. Ryder also testified that she: has never participated in development of any pelvic mesh device; has not authored a single peer-reviewed article on using polypropylene as a transvaginal surgical treatment for SUI or POP, let alone an article on the design, safety or efficacy of pelvic mesh products; and, has never managed, led or even participated in a clinical trial regarding the design, safety or efficacy of pelvic mesh products. *Id.* at 28:7-19. In light of this testimony, *Tyree* should control, not *In re C.R. Bard*. *See also Winebarger v. Bos. Sci. Corp.*, No. 2:13-cv-28892, 2015 U.S. Dist. LEXIS 53892, at *104 (S.D. W. Va. Apr. 24, 2015) ("The court is unpersuaded by [Defendants'] argument that [the expert] has sufficient experience with pelvic floor repair kits to opine as to the . . . design.").

Defendants respond to Plaintiffs' reliability arguments by pointing to the "materials lists" attached to Dr. Ryder's report. (Resp. at 8-9). However, although Dr. Ryder included a general list of materials reviewed, her opinion does not contain its basis and reasons and the facts or data considered in reaching it as required by Fed. R. Civ. P. 26(a)(2)(B)(i)-(ii). Additionally, the articles themselves do not provide a reliable basis because except for the 10 to 20 articles Dr. Ryder added, the remainder of the 382 articles were provided to her by Ethicon. Ryder Dep. Tr. at 44:9-17; 44:23-45:4; 45:17-46:4. Furthermore, during her deposition Dr. Ryder identified the articles most relevant and important in formulating her opinions, *id.* at 48:3-50:8, but neither the articles nor their underlying observational or experimental studies or meta-analysis reviews specifically or

directly address the issues of: the material properties of the Prolift mesh, polymer science or degradation of polypropylene, (*see* Mem. at 7). In short, while Defendants attempt to provide the basis for this opinion after the fact, the opinion contains no mention of the scientific methods or controls employed by Dr. Ryder.

II. Opinions Regarding Polypropylene Mesh Material, Mesh Pore Size, And Risk of Infection

Plaintiffs also seek exclusion of Dr. Ryder's opinions regarding polypropylene mesh material, mesh pore size, and risk of infection because Dr. Ryder is unqualified, the opinions are unreliable, and the opinions violate Rule 26. (Mem. at 12).

Although Defendants cite this Court's holding in *In re C.R. Bard*, (Resp. at 10), this case is distinguishable because Dr. Ryder's report does not contain a suggestion that she relied on her knowledge, experience, and scientific literature. Also, this particular holding pertains to reliability rather than qualification, as evidenced by Defendants arguing that "when an expert relies on scientific literature, as well as her own knowledge and experience, *her opinion is considered reliable*," (Resp. at 10) (emphasis added), meaning Defendants do not counter Plaintiffs' arguments regarding qualification, (*see generally id.* at 10-11). Nevertheless, as discussed in Plaintiffs' Mem., Dr. Ryder has limited, if any, experience or knowledge of the polypropylene material, porosity, and risk of infection. For instance, there is no evidence whatsoever of Dr. Ryder performing any analysis or comparison of implants to reach the conclusion that "particularly in relation to other implants," Prolift's pore size "has not presented increased risks of infection." Similarly, Dr. Ryder's clinical experience is lacking because by her very admission she has had only one case since 2000 dealing with mesh infection. Ryder Dep. Tr. at 146:11. In other words, the facts are similar to *Winebarger* in that Defendants argue that Dr. Ryder relied upon her experience in forming these opinions even though her "experience with such topics is lacking."

Winebarger, 2015 U.S. Dist. LEXIS 53892, at *102. Lastly, while Defendants repeatedly tout Dr. Ryder's review and reliance on medical literature, the opinion contains no citation or reference to the medical literature she specifically reviewed and the report itself does not discuss or cite the medical literature utilized by Dr. Ryder in forming these particular opinions, meaning these opinions are unverifiable and are without any scientific basis or methodology. As such, these opinions should be excluded. *See id.* at *117 ("[T]he court must ensure that the expert can 'explain how that experience leads to the conclusion reached, why that experience is a sufficient basis for the opinion, and how that experience is reliably applied to the facts.'") (quoting Fed. R. Evid. 702 advisory committee notes).

III. Opinions Regarding Mesh Degradation

Finally, Plaintiffs seek to exclude Dr. Ryder's opinions regarding mesh degradation because Dr. Ryder is unqualified, the opinions are unreliable, the opinions amount to non-expert lawyer arguments, and the opinions are irrelevant to the issues and scope of this case. (Mem. at 14). The Defendants essentially concede that Dr. Ryder has no specialized training specifically related to polypropylene or the scientific, chemical or structural make-up of the Prolift device. (Resp. at 11). They go on to say that she "does not need it" to opine about the clinical significance of any alleged degradation. (*Id.*) However, they rely upon her "detailed review" of the medical literature to offer said opinions, (*id.*); but, as previously pointed out by the Plaintiffs, no such "detailed review" ever occurred, (*see* Mem. at 5-7). Dr. Ryder has failed to identify reliance on even one peer reviewed article directly pertaining to mesh degradations. (*Id.*)

Further, any review of medical literature performed by Dr. Ryder pertaining to mesh degradation is unreliable because she admittedly only reviewed those articles provided to her by the defendants. (*Id.* at 16-17).

CONCLUSION

For the foregoing reasons, as well as the reasons set forth in Plaintiffs' Mot. and Mem., Plaintiffs respectfully request that their Motion be granted.

This 16th day of May, 2016.

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CERTIFICATE OF SERVICE

I hereby certify that on May 16, 2016, I electronically filed the foregoing document with the Clerk of the court using CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

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